GOVERNMENT OF INDIA
HEALTH AND FAMILY WELFARE
LOK SABHA

UNSTARRED QUESTION NO:3521
ANSWERED ON:22.12.2004
SALE OF BANNED DRUGS
Rao Shri Kavuru Samba Siva

Will the Minister of HEALTH AND FAMILY WELFARE be pleased to state:

(a) whether clinical trials in the United States have found that heart bypass surgery patients taking Bextra , and anti inflammatory drug in the same class as the newly banned `Rofecoxin`, increases the risk of stroke and heart attack;

(b) if so, whether the Bextra is a Valdecoxin sold in India under the banned names of Vazlus(Clenmark,) , Valcox(Unichem) , Valdiff(Cipla) and V-Cox (Lupin) among other ; and

(c) if so, the response of the Union Government on the sale of such drugs in the market?

Answer

THE MINISTER OF STATE IN THE MINISTRY OF HEALTH & FAMILY WELFARE (SMT. PANABAKA LAKSHMI)

(a) Government has no specific information about clinical trials in United State in heart by-pass surgery patients using Bextra, an anti-inflammatory drug in the same class as the drug `Rofecoxib`.

(b) Bextra is brand of Valdecoxib tablets, marketed internationally by M/s. Pharmacia. In India, a number of Pharmaceutical companies are marketing Valdecoxib tablets, under the brand names Vazlus (Glenmark), Volcox (Unichem), Valdiff (Cipla), and V-cox (Lupin) etc., among others.

(c) Valdecoxib is a COX-II inhibitor drug. Consequent to withdrawal of Rofecoxib, as recommended by the National Pharmacovigilance Advisory Committee, the manufacturers of COX-II inhibitor drugs are being advised to mention followings cautions on their label/package insert etc. -`The drug should be used with caution in patients with cardiovascular disorder`.